

MATTHEW MILLER (SBN 172661)  
matt.miller@dlapiper.com

ROBERT NOLAN (SBN 235738)  
robert.nolan@dlapiper.com

EVA K. SCHUELLER (SBN 237886)  
evi.schueller@dlapiper.com

**DLA PIPER LLP (US)**

555 Mission Street, Suite 2400  
San Francisco, California 94105

Tel: (415) 836-2500

Fax: (415) 836-2501

CHRISTOPHER OPRISON  
(pro hac vice application forthcoming)

chris.oprison@dlapiper.com

**DLA PIPER LLP (US)**

200 South Biscayne Boulevard, Suite 2500  
Miami, Florida 33131

Tel: (305) 423-8522

Fax: (305) 657-6366

Attorneys for Plaintiff  
Hemostemix Inc.

**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF CALIFORNIA**

HEMOSTEMIX INC.,

Plaintiff,

v.

MEDRIO, INC.,

Defendant.

CASE NO.:

**COMPLAINT FOR BREACH OF  
CONTRACT; CONVERSION; BREACH  
OF THE COVENANT OF GOOD FAITH  
AND FAIR DEALING; INTENTIONAL  
INTERFERENCE WITH PROSPECTIVE  
ECONOMIC ADVANTAGE**

**DEMAND FOR JURY TRIAL**

1 Plaintiff Hemostemix Inc. (“Hemostemix”), by and through its attorneys, DLA Piper LLP  
2 (US), alleges as follows:

3 **INTRODUCTION**

4 1. Hemostemix is the Food and Drug Administration (“FDA”) approved Sponsor of a  
5 clinical trial, HS 12-01, for ACP-01 (the “Clinical Trial”). ACP-01 is a therapeutic drug for the  
6 treatment of diseases of ischemia such as critical limb ischemia (“CLI”), angina and heart disease.  
7 For the Clinical Trial, ACP-01 is being tested at 17 sites in a double-blind placebo-controlled trial  
8 to demonstrate scientifically that it is a safe and efficacious treatment of CLI.

9 2. The Clinical Trial is at its midpoint. If ACP-01 successfully meets the endpoints of  
10 the Clinical Trial by the midpoint, Hemostemix can (1) announce to the world that ACP-01 is both  
11 safe and efficacious, (2) commence commercial treatments in jurisdictions where Phase II results  
12 are sufficient (Japan, South Korea, China, North America under Right to Try Laws and exemptions)  
13 and (3) commence its Phase III study.

14 3. As the Sponsor, Hemostemix has been the sole financial supporter of the Clinical  
15 Trial for six years. To date, Hemostemix has invested more than \$38 million in bringing ACP-01 to  
16 market. As the Sponsor, Hemostemix, and Hemostemix alone, is the sole and exclusive owner of all  
17 Clinical Trial intellectual property, including confidential documents, service data, clinical data, and  
18 any work product generated relating to the Clinical Trial for ACP-01 (collectively, “Clinical Trial  
19 Data”).

20 4. Hemostemix brings this action because its data hosting contractor, Defendant  
21 Medrio, Inc. (“Medrio”), is wrongfully refusing to return, or even to provide access to  
22 Hemostemix’s own Clinical Trial Data. Hemostemix has an absolute ownership right over the  
23 Clinical Trial Data and an absolute right to recover it upon demand.

24 5. Hemostemix has rightfully demanded the return of its data hosted by Medrio  
25 pursuant to a Master Services Agreement between Medrio and Hemostemix dated March 25, 2019  
26 (“Hemostemix/Medrio MSA”), attached hereto as **Exhibit A**, and the Medrio, Inc. Assignment and  
27 Assumption of Medrio Order Form And Consent (“Study Transfer Agreement”) dated March 26,  
28

2019, attached hereto as **Exhibit B** (collectively, the “Agreements”). Pursuant to the Hemostemix/Medrio MSA, Medrio agreed to provide data hosting services for Hemostemix’s Clinical Trial Data.

6. Medrio has wrongfully refused to provide Hemostemix access to its Clinical Trial Data. Medrio has further wrongfully and without legal basis provided a third party, Aspire Health Science, LLC (“Aspire”), with access to Hemostemix’s Clinical Trial Data to the exclusion of Hemostemix, the rightful owner of such data. Aspire admittedly has no ownership rights over the Clinical Trial Data.

7. The Clinical Trial Data in Medrio’s possession is central to the core business of Hemostemix. Hemostemix must comply with its U.S. FDA and Health Canada statutory reporting obligations regarding its Clinical Trial, which is prevented by Medrio’s failure and refusal to provide Hemostemix with access to its Clinical Trial Data.

8. Hemostemix wants to ensure that patients can continue to receive ACP-01 on a compassionate care basis, including a 19-year-old young man suffering from idiopathic pulmonary hypertension whose life was saved by ACP-01. He has lived approximately 9 years drug free since his treatment and desperately needs a second treatment. Medrio’s actions have impeded Hemostemix’s ability to continue the Clinical Trial and obtaining Phase II approval, all while interfering with the ability of individuals who are receiving this treatment—whether as participants in the Clinical Trial or on a compassionate care basis—from continuing this much needed treatment.

9. Medrio’s conduct is wrongful and harmful to Hemostemix. Its conduct impedes Hemostemix’s access to its own property. As a result, Medrio has caused Hemostemix significant, quantifiable harm. If permitted to continue, Medrio’s wrongful conduct will cause Hemostemix further severe irreparable and irreversible harm. Such harms include the spoliation of the Clinical Trial Data that has taken six years to compile, impeding access to the life-saving treatment of last resort to those patients who need it on a compassionate care basis, causing a risk of regulatory non-compliance of Hemostemix with the FDA, and causing a total loss of Hemostemix’s investment to date of \$38 million.



**STATEMENT OF FACTS**

**A. Hemostemix’s development of ACP-01—its life saving proprietary stem cell therapy**

16. Hemostemix was co-founded by Thomas Smeenck, its current CEO and President.

17. Since its formation, Hemostemix has been a clinical stage autologous cell-therapy biotechnology company. Its principal business is to develop, manufacture, and commercialize blood-derived cell therapies to treat diseases not addressed by current therapies.

18. Hemostemix has been and continues to be the owner of a patented, proprietary stem cell technology, ACP-01, that has been established through more than sixteen years of clinical research. ACP-01 is used for the treatment of ischemia, including obstructed arteries and other vascular diseases that include ischemic cardiomyopathy, and CLI, a severe form of peripheral artery disease (“PAD”) related to reduced blood flow to the limbs that can result in a host of complications, including nerve and tissue damage.

19. Approximately 50% of all CLI patients either die or require amputation of the affected limb within a year of diagnosis without treatment. Demand for treatment of CLI is increasing, as CLI predominantly affects diabetic individuals over the age of 50.

20. On or about August 21, 2015, the FDA cleared Hemostemix’s Investigational New Drug (“IND”) application for ACP-01 to expand the Clinical Trial for CLI.

21. Hemostemix serves as the Phase II Clinical Trial Sponsor in the approved application in order to enroll patients at clinical sites across the United States. That role has never changed. Hemostemix continues to serve as the sole Sponsor.

22. The FDA’s approval of Hemostemix’s IND was a major milestone in Hemostemix’s international Phase II double-blind, randomized, placebo-controlled Clinical Trial.

23. The Clinical Trial approved by the FDA was to investigate the safety and efficacy of Hemostemix’s patented stem cell technology, ACP-01, that has been subject to over 16 years of in-clinical research, including four other successful trials. ACP-01 is a proprietary autologous stem cell therapy that may be directed by a physician on a compassionate care basis to treat diseases of

1 ischemia such as angina and ischemic cardiomyopathy, CLI, and peripheral artery disease. More  
2 than 365 patients have been treated safely with ACP-01.

3 24. Hemostemix is conducting a randomized, placebo-based, double blind trial of the  
4 safety and efficacy of ACP-01 in patients with advanced CLI who have exhausted all other options  
5 to save their limbs from amputation.

6 25. Hemostemix's proprietary technology uses a patient's own stem cells to treat that  
7 patient's disease of ischemia such as CLI or PAD. Its proprietary technology includes methods for  
8 collecting from peripheral blood a synergetic cell population and manufacturing a personalized  
9 regenerative therapy that can be administered to a patient within seven days of the blood draw.

10 26. Throughout the course of the Clinical Trial, more than 17 Clinical Trial sites have  
11 been established across North America.

12 27. Each of the above Clinical Trial sites has produced data that belongs to Hemostemix  
13 that is hosted and held hostage by Medrio.

14 28. ACP-01 is at the midpoint in a Phase II clinical trial in Canada and the United States.  
15 "Midpoint" in this context means that a minimum of 42 patients enrolled in the study have been  
16 followed for 26 weeks. In a clinical trial, at the midpoint of the study, the parameters (or clinical  
17 data) of the study undergo an analysis by a statistician.

18 29. Based on published reports (to the 41st Annual Canadian Society for Vascular  
19 Surgery Meeting on September 14, 2019 from the lead investigators of the Clinical Trial at the  
20 University of British Columbia and the University of Toronto) that healing of ulcers and resolution  
21 of ischemic rest pain occurred in 83% of the patients, it is highly probable that the midpoint analysis  
22 in the Clinical Trial will provide the scientific proof that ACP-01 is efficacious and safe.

23 30. When the endpoints of a clinical trial are successfully proven by its midpoint, the  
24 Phase II trial and its related expenses can be stopped as the Phase II was scientifically validated and  
25 successfully concluded.

26 31. The Clinical Trial is at its midpoint. As such, Hemostemix must complete a valid and  
27 reliable midpoint statistical analysis to determine if ACP-01 is efficacious and safe, report that  
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determination to the FDA, and determine if all patients (totaling 95) need to be enrolled to complete the trial.

32. Upon completion of the midpoint data analyses confirming the safety and efficacy of ACP-01, Hemostemix will then be able to commercialize ACP-01 in jurisdictions where Phase II clinical trial results are sufficient for commercialization.

33. A successful Phase II Clinical Trial result would likely add at least \$300 million of commercial value to Hemostemix. Hemostemix cannot achieve this milestone so long as Medrio holds Hemostemix's Clinical Trial Data hostage and wrongfully refuses to return it to or provide Hemostemix access to such data, as required under the Hemostemix/Medrio MSA.

34. All Clinical Trial Data is the legal property of Hemostemix, as Sponsor. Medrio has never claimed such ownership over the Clinical Trial Data, nor could it.

**B. Hemostemix as Clinical Trial Sponsor has a duty and responsibility to ensure the proper and safe conduct of the Clinical Trial and ultimate accountability for all aspects of the Clinical Trial.**

35. As the Clinical Trial Sponsor, Hemostemix is legally responsible for all aspects of the Clinical Trial under FDA and Health Canada regulations. *See* 21 C.F.R. § 312.50. Hemostemix, as Sponsor, must provide oversight to the study and ensure the integrity of the data. Hemostemix is also subject to a series of regulatory requirements and responsibilities, which includes data management activities.

36. The "Good Clinical Practices" responsibilities are outlined in FDA guidance. *See* "E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)," U.S. Dep't of Health and Human Services, Food and Drug Administration, (March 2008). The FDA's "Good Clinical Practices" Guidance provides that:

*The sponsor is responsible for implementing and maintaining quality assurance and quality control systems* with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

*The sponsor is responsible for securing agreement* from all involved parties to ensure *direct access* [] to all trial-related sites, source data/documents, and reports

for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

***Quality control should be applied to each stage of data handling*** to ensure that all data are reliable and have been processed correctly.

Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, ***should be in writing***, as part of the protocol or in a separate agreement.

(*Id.*, §§ 5.1.1—5.1.4, at 25-26 (emphasis added).)

37. Pursuant to the FDA’s “Good Clinical Practices,” clinical trial Sponsors such as Hemostemix have a continuing responsibility to oversee data collection throughout the course of the entire clinical trial. In particular,

**Any change or correction to a CRF [Case Report Form] should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); *this applies to both written and electronic changes or corrections*** (see 5.18.4(n)). Sponsors should provide guidance to investigators and/or the investigators’ designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor’s designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.” (4.9.3)

(*Id.*, § 4.9.3 at 22 (emphasis added).)

38. Clinical trial Sponsors such as Hemostemix, “[w]hen using electronic trial data handing and/or remote electronic trial data systems,” such as that Medrio was contracted to provide, must “(f) [m]aintain adequate backup of the data[,] (g) [s]afeguard the blinding, if any (e.g., maintaining the blinding during data entry and processing[,] and (h) [e]nsure the integrity of the data, including any data that describe the context, content, and structure. . . .”

(*Id.*, § 5.5.3(f), (g), (h) at 27-28 (emphasis added).)

39. Clinical trial Sponsors such as Hemostemix are permitted to transfer trial-related duties and functions to a Clinical Research Organization (“CRO”). *See* 21 C.F.R. § 312.52. A Sponsor need not, but typically does, engage the services of a CRO. While a Sponsor promotes and financially backs the clinical trial, a CRO is essentially an intermediary or “middle-man” between



1 the Sponsor and the research sites.

2 40. A CRO typically is brought in to assist the Sponsor with trial-related duties, including  
3 writing the clinical trial protocol, submitting data on behalf of the Sponsor to the FDA, and  
4 monitoring the trial sites throughout the study. A CRO's services are necessarily limited and defined  
5 by agreement with the Sponsor.

6 41. At no time does a CRO gain a possessory or ownership interest over the clinical trial  
7 data generated during a clinical trial.

8 42. According to the FDA's Clinical Practices Guidance, regardless of delegating duties  
9 to a CRO, a Sponsor may not delegate ultimate accountability over the quality or integrity of the  
10 data. At all times, the Sponsor retains ultimate responsibility and accountability "for the quality and  
11 integrity of the trial data . . . ."

12 43. The FDA "Good Clinical Practices" Guidance makes clear this requirement, to wit:

13 *A sponsor may transfer any or all of the sponsor's trial-related duties and*  
14 *functions to a CRO, but the ultimate responsibility for the quality and integrity*  
15 *of the trial data always resides with the sponsor.* The CRO should implement  
quality assurance and quality control.

16 (*Id.*, § 5.2.1, at 26 (emphasis added).)

17 44. Finally, the FDA imposes on a clinical trial Sponsor such as Hemostemix the  
18 continuing obligation to act promptly in the event it learns of non-compliance with protocol, SOPs,  
19 Good Clinical Practices, or any regulatory requirements, to wit:

20 Noncompliance with the protocol, SOPs, GCP, and/or applicable regulatory  
21 requirement(s) by an investigator/institution, or by member(s) of the sponsor's staff  
should lead to prompt action by the sponsor to secure compliance.

22 *If noncompliance that significantly affects or has the potential to significantly*  
23 *affect human subject protection or reliability of trial results is discovered, the*  
24 *sponsor should perform a root cause analysis and implement appropriate*  
*corrective and preventive actions.*

25 (*Id.*, § 5.20.1 and ADDENDUM ("Noncompliance"), at 38 (emphasis added).)

26 45. The foregoing duties, obligations, responsibility and accountability relating to the  
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1 conduct and oversight of a clinical trial, including data management activities, fall squarely and  
2 solely on Hemostemix, as the Sponsor.

3 **C. Medrio is contractually bound to hold and securely store Hemostemix’s Clinical Trial**  
4 **Data on Medrio’s secure software platform but must return it only to Hemostemix, the**  
5 **Sponsor and owner of the data upon demand.**

6 46. Medrio purports to provide a secure software platform for hosting clinical research  
7 data owned by its customers, like Hemostemix.

8 47. Medrio also advertises its ability to capture its customers’ clinical trial data and  
9 maintain a “low total cost of ownership.”

10 48. Medrio advertises its knowledge of and ability to comply with the strict regulatory  
11 regime that governs clinical trial data prominently in multiple locations on its website, as follows:

12 **Full Peace of Mind for Regulatory Submission**

13 Medrio [Electronic Data Capture] meets or exceeds all global data collection  
14 regulations. From ICH/GCP and 21 CFR to GDPR and HIPAA, we give you the  
15 tools to focus on the trial with complete confidence that your data is compliant

16 49. On or about August 15, 2017, Hemostemix and Topstone Research Inc. (“Topstone”)  
17 executed a Master Services Agreement (“Hemostemix/Topstone MSA”). Pursuant to the  
18 Hemostemix/Topstone MSA, and in its capacity as then-CRO, Topstone agreed to provide clinical  
19 research monitoring services, project management, regulatory document and data management, and  
20 other related services in connection with the HS 12-01 Clinical Trial.

21 50. Among other responsibilities that Hemostemix delegated to Topstone were the  
22 management and secure preservation of the patient data from the Clinical Trial sites participating in  
23 the HS 12-01 Clinical Trial. Topstone, as CRO, provided such document and data management  
24 services to Hemostemix, as Sponsor, pursuant to a Master Services Agreement Topstone had  
25 previously executed with Medrio on or about September 27, 2016 (“Topstone/Medrio MSA”) that  
26 permitted Topstone to securely store data for multiple clients. The Topstone/Medrio MSA is  
27 attached hereto as **Exhibit C**.

28 51. Data generated from the Clinical Trial sites during the time Topstone served as CRO  
was securely uploaded and housed by Medrio for the benefit of Hemostemix.

1           52.     On March 25, 2019, Hemostemix and Medrio executed the Hemostemix/Medrio  
2 MSA that is attached hereto as **Exhibit A**. The Hemostemix/Medrio MSA became the controlling  
3 document for Medrio's hosting obligations relating to the HS 12-01 Clinical Trial data. Medrio was  
4 obligated to provide Hemostemix, *and Hemostemix alone*, access to and day-to-day responsibility  
5 for managing the Clinical Trial Data.

6           53.     Attached as Exhibit A to the Hemostemix/Medrio MSA was a "Medrio Order Form"  
7 ("Order Form") which reflected Hemostemix as the customer, the HS12-01 Clinical Trial study as  
8 the relevant study, and the study initiation date of April 5, 2019. The Order Form sets forth the  
9 "technical parameters" of the Clinical Trial Study as to Medrio's and Hemostemix's obligations  
10 under the Hemostemix/Medrio MSA.

11           54.     Shortly thereafter, on or about April 22-23, 2019, Hemostemix, Topstone, and  
12 Medrio entered into the Study Transfer Agreement that is attached hereto as **Exhibit B** with an  
13 effective date of March 26, 2019. Under the Study Transfer Agreement, Topstone transferred and  
14 assigned the rights and obligations arising under the Topstone/Medrio MSA and related order forms,  
15 including rights of access and receipt, to Hemostemix, the rightful owner of the Clinical Trial Data.

16           55.     A Study Transfer Agreement is required in order to validly transfer the covenants,  
17 obligations and rights (including access to and control of Clinical Trial Data while in Medrio's  
18 secure data hosting platform) under a prior Master Services Agreement, in this case, the  
19 Topstone/Medrio MSA. Indeed, it constitutes the only valid means by which rights and obligations  
20 under an MSA could be transferred to a new beneficiary.

21           56.     The Hemostemix/Medrio MSA was incorporated into the Study Transfer Agreement  
22 by reference.

23           57.     Under the Hemostemix/Medrio MSA, Medrio is obligated to "provide hosted  
24 services consisting of web-based access to Medrio's proprietary tools, and related support, as  
25 described in a Medrio Order Form . . . ," (Ex. A (Hemostemix/Medrio MSA), at ¶ 1(a)) as to all  
26 "Confidential Information" uploaded to the secure web-based platform.

27           58.     The Hemostemix/Medrio MSA includes a strict confidentiality provision to protect  
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1 Hemostemix's Confidential Information, defined to include Hemostemix's Clinical Trial Data  
2 received by Medrio from Hemostemix, to wit:

3       **"Confidential Information"** means all Clinical Data and Service Data, and all  
4 other information that one party and/or its affiliates (the "Receiving Party")  
5 receives from the other party and/or its affiliates (the "Disclosing Party") which  
6 either is marked "Confidential" or should be reasonably understood to be  
7 confidential. **"Service Data"** means all data contained in the Services including  
8 but not limited to configuration information, usage information, access logs,  
9 Clinical Data and other Customer-entered data. **"Clinical Data"** means all data  
10 entered by [Hemostemix] or third parties that is based on direct observation of, or  
11 reporting by or otherwise directly related to, a test subject/sample.

12 (Ex. A (Hemostemix/Medrio MSA), at ¶ 6(a) (emphasis added).)

13       59. The Hemostemix/Medrio MSA expressly prohibits Medrio from "using" or  
14 "divulging" Hemostemix's data, to wit:

15       **Obligations.** The Receiving Party [Medrio] will: (i) take reasonable precautions to  
16 protect all Confidential Information, and (ii) not use (except as expressly permitted  
17 herein) or divulge it to any third person. Except with respect to Service Data (which  
18 will *never* be disclosed), the Disclosing Party [Hemostemix] agrees that the  
19 foregoing will not apply 7 years after disclosure or if the Receiving Party can  
20 document that the information (a) is or has become generally available to the public;  
21 (b) was in its possession or known by it prior to receipt from the Disclosing Party;  
22 (c) was rightfully disclosed to it by a third party; (d) was independently developed  
23 without use of any Confidential Information of the Disclosing Party; or (e) is  
24 required by law or regulatory or judicial order to be disclosed.

25 (Ex. A (Hemostemix/Medrio MSA), at ¶ 6(b).) Medrio has violated this provision by not affording  
26 proper protection and confidential treatment to Hemostemix's Confidential Information. Medrio is  
27 providing Aspire access to Hemostemix's Clinical Trial Data without authority and without a Study  
28 Transfer Agreement, and doing so to the exclusion of Hemostemix.

29       60. The Hemostemix/Medrio MSA expressly requires Medrio to indemnify, defend and  
30 hold harmless Hemostemix in the event of any breach by Medrio of the MSA causing harm to  
31 Hemostemix, to wit:

32       Medrio will indemnify, defend and hold harmless [Hemostemix] . . . from all losses,  
33 liabilities, costs, damages, penalties, fines and expenses, including reasonable  
34 attorneys' fees (collectively, "Losses") arising from any third-party claims,

demands, threats, suits or proceedings (each, a “Claim”) arising from any alleged breach by Medrio of Section 8 (Compliance with Applicable Laws), or from any allegation that the Services infringe, violate, or misappropriate the intellectual property rights of any third party.

(Ex. A (Hemostemix/Medrio MSA), at ¶ 9(a) (“Indemnities”).) Medrio has violated the Hemostemix/Medrio MSA by not affording proper protection and confidential treatment to Hemostemix’s Confidential Information by providing Aspire access to Hemostemix’s Clinical Trial Data without authority to do so and without a Study Transfer Agreement, and doing so to the exclusion of Hemostemix. Medrio is obligated under paragraph 9(a) to indemnify Hemostemix for all losses and damage it has caused to Hemostemix.

61. The Hemostemix/Medrio MSA makes explicitly clear that the “Customer,” here Hemostemix, “will retain all rights in any data or content created or uploaded by [Hemostemix] while using the Services.” (Ex. A (Hemostemix/Medrio MSA), at ¶ 11 (“Proprietary Rights”).)

62. The Hemostemix/Medrio MSA includes representations and warranties by Medrio that “it will use reasonable efforts consistent with prevailing industry standards to minimize errors and interruptions in the Services.” (Ex. A (Hemostemix/Medrio MSA), at ¶ 11 (“Warranties”).) Medrio has violated this provision by blocking Hemostemix’s access to and disrupting the Services related to the hosting of Hemostemix’s Clinical Trial Data.

63. At no point in time did ownership over Hemostemix’s Clinical Trial Data ever vest in or transfer Medrio, or any other entity or individual. The Clinical Trial Data was at all times and continues to be the sole and exclusive property of Hemostemix.

64. Medrio has used and divulged Hemostemix’s Clinical Trial Data in violation of the Hemostemix/Medrio MSA.

**D. Medrio refuses to provide Hemostemix access to its Clinical Trial Data in violation of the Hemostemix/Medrio MSA**

65. Upon information and belief, unbeknownst to Hemostemix, in or about November 2019, Medrio executed a separate Master Services Agreement with Aspire, Hemostemix’s former CRO, that is materially identical to the Hemostemix/Medrio MSA and through which Aspire has

1 purported to assume control over Hemostemix's Clinical Trial Data.

2 66. Aspire had no authority to assume control over Hemostemix's Clinical Trial Data or  
3 to effectively block Hemostemix's access to its own Clinical Trial Data.

4 67. Purportedly as a consequence of Aspire's MSA with Medrio, Medrio has blocked  
5 Hemostemix's access to its Clinical Trial Data and transferred control over such data to Aspire.  
6 Medrio was never authorized to do so.

7 68. At no time has the Hemostemix/Medrio MSA been rescinded or terminated by  
8 Hemostemix or Medrio.

9 69. At no time has Hemostemix executed a Study Transfer Agreement with Medrio and  
10 Aspire that would transfer access to and authority and control over the HS 12-01 Clinical Trial Data  
11 to Aspire.

12 70. Hemostemix has demanded that Medrio provide access to its Clinical Trial Data for  
13 all active Clinical Trial sites hosted by Medrio, and has also demanded the return of such data.  
14 Medrio refused such demands.

15 71. By letter dated August 27, 2020 to both Hemostemix's and Aspire's counsel, Medrio  
16 refused to grant Hemostemix access to its own data, citing instructions by Aspire. In subsequent  
17 discussions, Medrio continues to refuse Hemostemix access to the Clinical Trial Data.

18 72. Aspire is not a party to either the Hemostemix/Medrio MSA, the  
19 Hemostemix/Topstone MSA or the Study Transfer Agreement.

20 73. As explained in Hemostemix's correspondence to Medrio's counsel dated September  
21 3, 2020, attached hereto as **Exhibit D**, Medrio's contractual obligation to return and/or provide  
22 access to Hemostemix's data is independent of any obligation Medrio now claims it owes to Aspire.

23 74. On or about September 22, 2020, Medrio terminated access to the secure data hosting  
24 platform to *all clinical trial sites*. The effect of this step has been to prevent and preclude the Clinical  
25 Trial sites, participating in the HS 12-01 Clinical Trial, from uploading test results to the platform,  
26 including each trial subject's monthly follow-up visit information and data—the very information  
27 that is critical and central to the Clinical Trial.

**FIRST CAUSE OF ACTION  
(BREACH OF CONTRACT)**

75. Hemostemix adopts and reasserts the allegations contained in paragraphs 1 through 74 as if fully set forth herein.

76. Hemostemix and Medrio executed the binding and enforceable Hemostemix/Medrio MSA on or about March 25, 2019.

77. Hemostemix, Topstone and Medrio executed a binding and enforceable Study Transfer Agreement on or about April 22-23, 2019 with an effective date of March 26, 2019.

78. The Study Transfer Agreement incorporates by reference all terms of the Hemostemix/Medrio MSA.

79. Under the Agreements, Medrio agreed to protect and secure the confidentiality of Hemostemix's Clinical Trial Data.

80. Under the Agreements, Medrio agreed that it would not use or divulge Hemostemix's Clinical Trial Data.

81. The Hemostemix/Medrio MSA provides that Medrio's duty to protect the confidentiality of Hemostemix's Clinical Trial Data survives termination or expiration of such agreement.

82. Hemostemix has performed all obligations owed under the Hemostemix/Medrio MSA and the Study Transfer Agreement.

83. Despite its obligation to do so, Medrio refuses Hemostemix access to Hemostemix's confidential Clinical Trial Data.

84. Despite its obligation to do so, Medrio refuses to return the Clinical Trial Data to Hemostemix.

85. Despite its obligation not to do so, Medrio has released, provided access and divulged Hemostemix's Confidential Information, including the Clinical Trial Data, to Aspire, a third-party.

86. Despite its obligation not to do so, Medrio has obstructed and blocked Hemostemix from being able to exercise dominion and control over the documents and data being hosted by

Medrio.

87. Despite its obligations to do so, Medrio has violated applicable laws governing the protection and confidentiality of Hemostemix's Confidential Information.

88. Each violation set forth herein constitutes a separate breach and event of default of the Hemostemix/Medrio MSA.

89. As a direct and proximate result of Medrio's multiple breaches of the Hemostemix/Medrio MSA, Hemostemix has suffered harm and been put at risk of future harm.

90. Hemostemix is thus entitled to damages subject to proof and as set forth below in its Prayer for Relief.

**SECOND CAUSE OF ACTION  
(CONVERSION)**

91. Hemostemix adopts and reasserts the allegations contained in paragraphs 1 through 74 as if fully set forth herein.

92. Hemostemix provided its Clinical Trial Data over which it has sole and exclusive ownership to Medrio for the sole purpose that Clinical Trial Data be housed on Medrio's secure software platform as reflected in Hemostemix/Medrio MSA.

93. Hemostemix's Clinical Trial Data remains the exclusive property of Hemostemix.

94. Hemostemix has repeatedly demanded the return of its Clinical Trial Data.

95. Medrio has no right to retain or use Hemostemix's property and Medrio was and is required to return the Clinical Trial Data to Hemostemix upon demand.

96. Hemostemix has not consented in any way to Medrio retaining and refusing to return its Clinical Trial Data.

97. Medrio has exercised dominion over Hemostemix's Clinical Trial Data to the exclusion of Hemostemix in bad faith.

98. Hemostemix has been damaged in an amount to be proven at trial as a result of Medrio's actions in converting Hemostemix's property.

99. Hemostemix is thus entitled to damages subject to proof and as set forth below in its



1 Prayer for Relief, including punitive damages.

2 **THIRD CAUSE OF ACTION**  
3 **(BREACH OF THE COVENANT OF GOOD FAITH AND FAIR DEALING)**

4 100. Hemostemix adopts and reasserts the allegations contained in paragraphs 1 through  
5 74 as if fully set forth herein.

6 101. As described above, Medrio made promises and representations to Hemostemix that  
7 it would comply with all applicable laws, regulations, and industry best practices.

8 102. These promises and representations became a part of the Hemostemix/Medrio MSA  
9 and the Study Transfer Agreement with Medrio.

10 103. Any discretion Medrio had in the specifics of how it met the applicable laws and  
11 industry standards was governed by an implied covenant of good faith and fair dealing.

12 104. Medrio breached this implied covenant when it engaged in unlawful practices in  
13 violation of its Agreements with Hemostemix. These acts and omissions included: representing that  
14 it would protect Hemostemix's ownership rights over its Clinical Trial Data as well as maintain  
15 regulatory compliance and procedures to safeguard the security of Hemostemix's Clinical Trial  
16 Data.

17 105. Hemostemix did all or substantially all of the significant things that the  
18 Hemostemix/Medrio MSA and the Study Transfer Agreement required it to do. All conditions for  
19 Medrio's performance were satisfied.

20 106. Hemostemix has been harmed by Medrio's breach of the implied covenant of good  
21 faith and fair dealing.

22 107. Medrio is liable for this breach of these implied covenants whether or not it is found  
23 to have breached any specific express contractual term.

24 108. Hemostemix is thus entitled to damages subject to proof and as set forth below in its  
25 Prayer for Relief.

**FOURTH CAUSE OF ACTION  
(INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC RELATIONS)**

109. Hemostemix adopts and reasserts the allegations contained in paragraphs 1 through 74 as if fully set forth herein.

110. Hemostemix and the federal Food and Drug Administration are engaged in an economic relationship by which Hemostemix is the official Sponsor for the HS 12-01 Clinical Trial of ACP-01. This relationship is highly likely to result in an economic benefit to Hemostemix.

111. Medrio well knows of Hemostemix's exclusive relationship with the FDA as the sole ACP-01 FDA-approved Sponsor.

112. Medrio has engaged in wrongful conduct by refusing to return or allow access to Hemostemix of its own Clinical Trial Data, which constitutes conversion, and by using and/or disclosing Hemostemix's confidential Clinical Trial Data in violation of its Agreements with Hemostemix, and state and federal law protecting data security and consumer privacy.

113. Medrio knew that by wrongfully breaching its Agreements with Hemostemix and converting its Clinical Trial Data, it would interfere with Hemostemix's relationship with the FDA and Hemostemix's Clinical Trial.

114. Medrio's actions have in fact delayed progress of Hemostemix's FDA trial and threaten to delay if not prevent entirely ACP-01's time to market.

115. Medrio has acted in bad faith.

116. Hemostemix was harmed as a result of Medrio's conduct, and is thus entitled to damages subject to proof and as set forth below in its Prayer for Relief, including punitive damages.

**PRAYER FOR RELIEF**

**WHEREFORE**, Hemostemix prays for judgment against Medrio as follows:

- 1) For damages arising from the breaches of the Hemostemix/Medrio MSA, according to proof;
- 2) For compensatory, incidental, special, and consequential damages arising from the Medrio's breaches and tortious conduct at issue herein, according to proof;

- 1           3)       For punitive damages;
- 2           4)       For indemnification, including attorneys' fees, costs of suit, and any other statutory
- 3 recoveries permitted;
- 4           5)       For specific performance to require Medrio to provide all Clinical Trial Data to
- 5 Hemostemix without further delay, and to stop providing access of such Clinical Trial Data to any
- 6 and all third parties such as Aspire; and
- 7           6)       For such other, further and different relief as the Court deems just and proper.
- 8

9       Dated: October 28, 2020

**DLA PIPER LLP (US)**

10

11                               By: /s/ Matthew Miller

12                               MATTHEW MILLER

13                               555 Mission Street, Suite 2400

14                               San Francisco, California 94105

15                               Tel: (415) 836-2500

16                               Fax: (415) 836-2501

17                               matt.miller@dlapiper.com

18                               CHRISTOPHER OPRISON

19                               (pro hac vice application forthcoming)

20                               **DLA PIPER LLP (US)**

21                               200 South Biscayne Boulevard, Suite 2500

22                               Miami, Florida 33131

23                               Tel: (305) 423-8522

24                               Fax: (305) 657-6366

25                               chris.oprison@dlapiper.com

26                               *Attorneys for Plaintiff*

27                               *Hemostemix Inc.*

28

**REQUEST FOR JURY TRIAL**

Hemostemix Inc. hereby demands a jury trial.

Dated: October 28, 2020

**DLA PIPER LLP (US)**

By: /s/ Matthew Miller

MATTHEW MILLER

555 Mission Street, Suite 2400

San Francisco, California 94105

Tel: (415) 836-2500

Fax: (415) 836-2501

matt.miller@dlapiper.com

CHRISTOPHER OPRISON

(pro hac vice application forthcoming)

**DLA PIPER LLP (US)**

200 South Biscayne Boulevard, Suite 2500

Miami, Florida 33131

Tel: (305) 423-8522

Fax: (305) 657-6366

chris.oprison@dlapiper.com

*Attorneys for Plaintiff*

*Hemostemix Inc.*

# **EXHIBIT A**



## MEDRIO, INC. MASTER SERVICES AGREEMENT

**CUSTOMER:** Hemostemix Inc, a AB [ STATE ] corporation

**ADDRESS:** 2150, 300 – 5 Ave SW Calgary, AB T2P 3C4

**EFFECTIVE DATE:** 03/25/2019 (MM/DD/YYYY)

This Master Services Agreement (with any Order Form, the "Agreement") is entered into by Medrio, Inc., a Delaware corporation, and the Customer identified above, as of the Effective Date shown above.

### 1. SERVICES AND SUPPORT.

a. Services. Medrio will provide hosted services consisting of web-based access to Medrio's proprietary tools, and related support, as described in a Medrio Order Form (each, an "Order Form"). A separate Order Form is required for each service, study or groups of studies, as expressly stated in the Order Form.

b. Equipment. Customer is responsible for all equipment and ancillary services for gaining access to and using the Services (collectively, "Equipment"), and for ensuring that the Equipment is compatible with the Services in accordance with Medrio's then-current published policies. Customer is also responsible for maintaining the security of the Equipment and its account.

c. Browser Support. The documentation with each release will specify supported browsers. New browsers may be required for new functionality. Medrio is not required to support browsers no longer supported by their original developers. Medrio will provide reasonable notice when deprecating support for a particular browser.

d. Support. Medrio will provide Level-2 technical support (or other support agreed to on an Order Form), through e-mail or telephone. Level-2 means Medrio supports study designers, builders, and administrators; Medrio does not directly support site users and study subjects. Medrio will provide 99.5% Uptime (24x7x365) of the Services, per calendar month, excluding regularly scheduled maintenance times and excluding outages beyond Medrio's control (e.g., caused by Customer's computers or connectivity, or a general internet failure). "Uptime" means availability and access to the Services.

d. Upgrades. Upgrades to the Services may be made in Medrio's sole discretion.

2. **STUDIES.** The terms of each Order Form will apply solely to the study (or group of studies) identified therein. Upon completion of each study, Customer will notify Medrio, who will archive the study or group of studies. Maintaining the study live after completion may be requested but will be subject to Medrio's then-current policies, including additional fees.

3. **REGISTRATION; LOG-IN INFORMATION.** Customer will be given log-in user names and initial passwords (the "Log-In Information"). Customer is responsible for maintaining the confidentiality and security of its Log-In Information, and for all activities resulting from access to the Services using the Log-In Information, or otherwise gained via its registered account. Customer will immediately notify Medrio at [security@medrio.com](mailto:security@medrio.com) of any actual or suspected unauthorized access or similar breach of security.





4. **FEES.** Medrio will invoice Customer electronically at the beginning of each calendar month. All undisputed invoices must be paid within 30 days of the invoice date. Adjustments will only be made if Customer contacts Medrio at [invoicing@medrio.com](mailto:invoicing@medrio.com) with confirmed receipt within 60 days of the date of the disputed invoice. Undisputed and unpaid invoice balances are subject to a finance charge of 1.5% per month, or as permitted by law, if lower, plus all expenses of collection. Customer is responsible for all duties, withholdings and taxes associated with the Services other than taxes based on Medrio's net income. Any discounts provided for "up-front payment" must be paid within 60 days of invoice to be earned; otherwise, the discounts will be reversed and Customer will be invoiced for undiscounted fees.

5. **RESTRICTIONS ON USE.** This is a contract for services only. The software used to provide the Services will be installed, accessed and maintained only by or for Medrio; no license is granted in it. Customer will not directly or indirectly: reverse engineer, decompile, disassemble or otherwise attempt to discover the source code, object code or underlying structure, ideas or algorithms of the Services or any software or documentation related to the Services ("Software"); modify, translate, or create derivative works based on the Services or any Software; copy, rent, lease, distribute, pledge, assign, or otherwise transfer or encumber rights to the Services or any Software; or use the Services or any Software for timesharing or service bureau purposes or otherwise for the benefit of a third party.

6. **CONFIDENTIAL INFORMATION.**

a. **Definitions.** "Confidential Information" means all Clinical Data and Service Data, and all other information that one party and/or its affiliates (the "Receiving Party") receives from the other party and/or its affiliates (the "Disclosing Party") which either is marked "Confidential" or should be reasonably understood to be confidential. "Service Data" means all data contained in the Services including but not limited to configuration information, usage information, access logs, Clinical Data and other Customer-entered data. "Clinical Data" means all data entered by Customer or third parties that is based on direct observation of, or reporting by or otherwise directly related to, a test subject/sample.

b. **Obligations.** The Receiving Party will: (i) take reasonable precautions to protect all Confidential Information, and (ii) not use (except as expressly permitted herein) or divulge it to any third person. Except with respect to Service Data (which will never be disclosed), the Disclosing Party agrees that the foregoing will not apply 7 years after disclosure or if the Receiving Party can document that the information (a) is or has become generally available to the public; (b) was in its possession or known by it prior to receipt from the Disclosing Party; (c) was rightfully disclosed to it by a third party; (d) was independently developed without use of any Confidential Information of the Disclosing Party; or (e) is required by law or regulatory or judicial order to be disclosed.

c. **Medrio's Use of Service Data.** Notwithstanding anything to the contrary in this Agreement, Medrio may collect and use, on an entirely anonymous and aggregated basis, the Service Data, *provided however* that no such use will identify or otherwise be linked to Customer or any of its Clinical Data (or any test subject related to such Clinical Data), or otherwise make it possible for any third party to associate Customer with any services provided by Medrio, or to associate any Clinical Data with any test subject.

7. **TERM AND TERMINATION.**

a. **Term.** This Agreement will commence on the Effective Date and will continue for 1 year (the "Initial Term"). It will automatically renew for subsequent one-year terms (each, a "Renewal Term"), unless one party notifies the other, no less than 60 days before the end of the Initial Term or any Renewal Term, of its intention not to renew. If either party notifies the other of its intention not to renew, the Agreement will continue nonetheless until the conclusion of all studies commenced under Order Forms fully executed as of the non-renewal notice date. The Initial Term and any Renewal Term(s) are collectively referred to as the "Term."



b. Termination for Cause. Either party may terminate this Agreement if the other party breaches a material obligation but does not cure to the reasonable satisfaction of the other party by 30 days after written notice of the breach. Either party may terminate immediately on written notice if the other party becomes insolvent, is dissolved or liquidated (except for reorganization), makes a general assignment for the benefit of its creditors, files or has filed against it a petition for bankruptcy, or has a receiver appointed for a substantial part of its assets.

c. Other Termination by Customer.

- (i) In the event Customer has paid in full for the amounts due on all executed Order Forms, including amounts that have not yet been invoiced, Customer may terminate this Agreement with 30 days' written notice.
- (ii) Where an Order Form is for an individual study, Customer may request early termination of an Order Form in the event a study is cancelled, is halted by a regulatory agency, or is halted for safety reasons. Medrio may grant such a request in its discretion if it determines that the documentation warrants an early termination. In the event of any termination requested by Customer under this Subsection 7(c)(ii), there will be no refund of any pre-paid amounts. Medrio will, however, apply a credit of such unused pre-paid amounts to any future Order Forms.
- (iii) Where an Order Form is for concurrent multi-study or bulk study pricing, commonly referred to as "Preferred" or "Enterprise" pricing, Customer will have no right to terminate for convenience and Customer shall remain obligated for the full commitment.

**8. COMPLIANCE WITH APPLICABLE LAWS.** Each party will comply with all laws and regulations applicable to the Services ("Applicable Laws"). If Customer is conducting studies in the US, this includes but is not limited to the Health Insurance Portability and Accountability Act ("HIPAA") governing Personal Health Information ("PHI"), as defined in the Privacy Rule and the Security Rule of HIPAA. When using the Services, Customer will ensure that its staff is fully trained in handling PHI in compliance with all Applicable Laws, that PHI collected by Customer is correctly designated as such, and that appropriate controls on access to and use of the Services are implemented and monitored by Customer. Customer understands and agrees that Medrio will have no responsibility or liability of any kind relating to the dissemination or use of any Clinical Data or any material derived from any Clinical Data once it leaves the direct control of Medrio (e.g., by screen shot, export, report, etc.). Customer will not remove or export from the United States or allow the export or re-export of the Services, or any direct product thereof, in violation of any restrictions, laws or regulations of the United States Department of Commerce, the United States Department of Treasury Office of Foreign Assets Control, or any other United States or foreign agency or authority. In compliance with FDA Title 21 CFR Part 11, Customer will be responsible for validating the software based on its own configuration and intended use.

**9. INDEMNITIES.**

a. Medrio. Medrio will indemnify, defend and hold harmless Customer, and its parents, subsidiaries, affiliates, officers, directors and employees, from all losses, liabilities, costs, damages, penalties, fines and expenses, including reasonable attorneys' fees (collectively, "Losses") arising from any third-party claims, demands, threats, suits or proceedings (each, a "Claim") arising from any alleged breach by Medrio of Section 8 (Compliance with Applicable Laws), or from any allegation that the Services infringe, violate or misappropriate the intellectual property rights of any third party.





b. **Customer.** Customer will indemnify, defend and hold Medrio, and its parents, subsidiaries, affiliates, officers, directors and employees, harmless from all Losses arising from any Claim arising from any act or omission of Customer in breach of this Agreement, including but not limited to any violation of Applicable Law in its use of the Services.

c. **Process.** If any Claim is asserted, the party seeking indemnification will promptly notify the indemnifying party of all material details of such Claim known to it. The party seeking indemnification will cooperate with the indemnifying party in the defense of the Claim, and will not compromise or otherwise settle any such Claim without the indemnifying party's prior written consent.

**10. AUDITS.** Upon reasonable notice and during regular business hours, Customer or its agents may inspect Medrio's facilities and may audit records, including contracts, copies, files, records, accounts and other documents and materials in Medrio's control, relating to the Services. Medrio will provide commercially reasonable assistance in the inspection or audit. Customer's right to audit will continue for 1 year after termination or expiration of this Agreement, or longer if required by Applicable Laws.

**11. PROPRIETARY RIGHTS.** Customer acquires only the right to use the Services; it does not acquire any rights of ownership in or to the Services or any technology used to provide the Services. All rights, title and interest in the Services and (other than content created by Customer), the material on the Medrio Web site, including without limitation all intellectual property rights therein, will at all times exclusively remain with Medrio. All rights not expressly granted are reserved to Medrio. Customer will retain all rights in any data or content created or uploaded by Customer while using the Services.

**12. WARRANTIES.** Each party represents and warrants that it has the power and authority to enter into and fully perform its obligations under this Agreement. Medrio represents and warrants that it will use reasonable efforts consistent with prevailing industry standards to minimize errors and interruptions in the Services.

**13. DISCLAIMERS OF WARRANTIES.** EXCEPT AS EXPRESSLY STATED HEREIN, AND TO THE MAXIMUM EXTENT PERMITTED BY LAW, MEDRIO MAKES NO, AND HEREBY DISCLAIMS, ANY REPRESENTATION, WARRANTY OR GUARANTY, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SERVICES.

**14. LIMITATION OF LIABILITY.** EXCEPT WITH RESPECT TO (i) FEES PAYABLE UNDER SECTION 4, (ii) INDEMNIFIED CLAIMS UNDER SECTION 9, (iii) BREACH OF SECTION 6 (CONFIDENTIAL INFORMATION), AND (iv) INFRINGEMENT OF A PARTY'S INTELLECTUAL PROPERTY RIGHTS, NEITHER PARTY OR ITS OFFICERS, AFFILIATES, REPRESENTATIVES, SUPPLIERS, CONTRACTORS OR EMPLOYEES WILL BE LIABLE UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY FOR ANY AMOUNTS THAT, TOGETHER WITH AMOUNTS ASSOCIATED WITH ALL OTHER CLAIMS, EXCEED THE FEES PAID BY CUSTOMER TO MEDRIO FOR THE SERVICES UNDER THE APPLICABLE ORDER FORM IN THE 12 MONTHS PRIOR TO THE ACT THAT GAVE RISE TO THE LIABILITY. IN NO EVENT WILL EITHER PARTY BE DIRECTLY LIABLE TO THE OTHER PARTY FOR ANY PUNITIVE OR EXEMPLARY DAMAGES.

**15. SECURITY OF DATA.** During the Term Medrio will (a) maintain policies and procedures, and fully document the content and implementation of Medrio's administrative, technical, and physical safeguards, to protect the Service Data; (b) conduct periodic risk assessments (at a minimum, annually) and update its security program accordingly; and (c) notify Customer, within no more than 72 hours, if it reasonably believes there has been unauthorized access to or acquisition of any Service Data. All Medrio employees and contractors with access to Service Data will be trained in procedures to ensure compliance with Applicable Laws.


**16. INSURANCE.** Medrio will maintain a valid policy of workers' compensation insurance for protection against any injuries suffered by Medrio's agents, employees, or contractors while performing its obligations




hereunder, and commercial general liability insurance for protection against any personal property damage or liability suffered by Customer or any third party as a result of acts of omission of Medrio or its agents, employees or contractors. Medrio will provide Customer with evidence of such insurance coverage, upon reasonable written request.

**17. GENERAL.** Medrio is and will remain an independent contractor. Nothing in this Agreement will be construed to create an employer/employee, joint venture, or partnership relationship between the parties. Neither party will have any authority to make any promise, representation, or contract on behalf of the other party. Neither party may assign or otherwise transfer its rights under this Agreement without the prior written consent of the other party (which may be given via e-mail), provided however that either party may assign this Agreement, provided that it gives written notice (which may be via e-mail), in the event of a merger, sale or acquisition of it, or a sale of all or substantially all of its assets relating to this Agreement. Neither party will issue any press release or other publicity without the prior written consent of the other (which may be given via e-mail), provided however that Medrio may during the Term include Customer on its customer list. If any provision of this Agreement is found to be unenforceable or invalid, that provision will be limited to the minimum extent necessary. This Agreement, with any Order Form effective on or after the Effective Date, is the complete and exclusive statement of the mutual understanding of the parties. It supersedes and cancels all previous written and oral agreements, communications and other understandings relating to this Agreement. All waivers and modifications must be in a writing signed by both parties, except as otherwise provided herein. This Agreement will be governed by the laws of California without regard to any conflict of laws principle that would refer its construction to the laws of another jurisdiction. Each party irrevocably submits to the personal jurisdiction of the courts located in San Francisco County, California, which it agrees will have exclusive jurisdiction over this Agreement and the parties; venue will be proper in any such court. Upon termination or expiration of this Agreement, Sections 4 (as to unpaid amounts), 5, 6, 7(c) (last sentence), 8 through 14, inclusive, and this Section 17 will survive. Commencing 90 days from termination or expiration, Medrio may, but is not obligated to, delete archived Service Data (as permitted under Applicable Laws). If there is any dispute under this Agreement, the parties will work in good faith, for a period of no less than thirty (30) days from the date of written notice of the dispute, to resolve the matter informally, before initiating any formal proceeding. All notices will be in writing and addressed as stated below, and will be deemed given upon actual receipt, or when receipt is electronically confirmed, if transmitted by e-mail. Notices to Medrio will be addressed, "Attn: Legal Dept."

**Medrio, Inc.**

By   
DocuSigned by:  
22BF97EEB74347B...  
 Name Nathan Weems  
 Title CFO  
 Date 3/25/2019  
 Address 345 California Street, Suite 325  
San Francisco, CA 94104  
 Email for Notices notices@medrio.com

**Customer**

**Hemostemix Inc.**  
 By   
 Name Kyle Makofka  
 Title CEO  
 Date 03/25/2019  
 Address 2150, 300 – 5 Ave SW  
Calgary, AB Canada T2P 3C4  
 Email for Notices kmakofka@hemostemix.com





## Addendum (Exhibit A for MSAs)

### Medrio Order Form

#### BILLING INFORMATION

Customer	Hemostemix Inc.
Study	HS12-01
Medrio Account Manager	Nick LaBounty
Study Initiation Date	04/05/2019
Billing Commencement Date	Upon Signature
Customer Billing Contact	Reg Cooper
Customer Email	rcooper@hemostemix.com

#### TECHNICAL PARAMETERS

Number of Login Users	Medrio caps the number of users to prevent misuse. Please contact your Account Manager if you will exceed these maximums. Studies up to a 12-month duration: 200, Studies greater than a 12-month duration: 600.
Enrolled Subjects	Unlimited
Data Points	1,000,000 per study maximum (more can be purchased as a separate module). Overage Fee: for every 250K data points over original 1M, 10% of base monthly price will be paid monthly in addition to original subscription fees
Dictionary Coding	YES (Customer is responsible for any applicable 3rd party licenses for the dictionary(s) they select from Medrio's list of supported dictionaries)
Randomization	YES
ePRO	NO
eCRF File Attachments	YES
Standard Technical Support	YES: 24/7 Level 2 included by phone and email all in English

#### SERVICE CONFIGURATION

PRODUCT NAME	CHARGE	TOTAL
Medrio EDC	Monthly billing 7 Months @ \$4,000/month 3 Months @ \$2,000/month	Initial Payment: \$4,000
Initial Payment Total		\$4,000
Contract Lifetime		10 months
Total Contract Value		\$34,000

**PROFESSIONAL SERVICES**

*Hourly work: hours in addition to the amounts specified in this Order Form are billable under this Order Form, but only when pre-authorized.*

*Reasonable pass-through expenses for travel and other incidentals associated with professional services such as training will be billed separately.*

**Medrio Master Services Agreement Effective Date: 3/20/2019**

This Order Form may be executed in two or more counterparts (which may include digital signatures and PDF and similar digital format counterparts), each of which shall be deemed to be an original, but all of which together shall constitute one agreement binding on the parties, notwithstanding that both parties are not signatories to the original or the same counterpart.

By signing below, each party represents and warrants that it has full power and authority to accept the terms of this Order Form, and that it agrees to be bound by the Medrio Master Services Agreement identified above, which is incorporated by reference and made a part of this Order Form.


In the event this Order Form references an MSA that has expired, both parties agree to renew that existing and expired MSA for the term of this Order Form. If no term is explicitly stated or deduced by the implicit length of service provided by this Order Form, then the term will be considered month-to-month with either party able to cancel with 30 days' notice.

IN WITNESS WHEREOF, this Order Form has been executed by persons duly authorized as of the later date of execution by the parties.

**Medrio, Inc.**

DocuSigned by:  
Signature: Nathan Weems  
22BF97EEB74347B...  
Name: Nathan Weems  
Title: CFO  
Date: 3/25/2019

**Customer: Hemostemix Inc.**

Signature:   
Name: Kyle Makofka  
Title: CEO  
Date: 03/25/2019

# **EXHIBIT B**



**MEDRIO, INC. ASSIGNMENT AND ASSUMPTION OF MEDRIO ORDER FORM AND CONSENT  
(STUDY TRANSFER AGREEMENT)**

**EFFECTIVE DATE: 03/26/219**

**TRANSFEROR: Topstone Research Inc, a Toronto Corporation**

**TRANSFEROR ADDRESS: 118 Turnpike Road, Southborough, MA 01772**

**TRANSFeree: Hemostemix Inc, a AB corporation**

**TRANSFeree ADDRESS: 2150, 300 – 5 Ave SW Calgary, AB T2P 3C4**

**NAME OF STUDY: HS 12-01**

**EFFECTIVE DATE OF ORDER FORM: 04/05/2019**

**EFFECTIVE DATE OF TRANSFeree MASTER SERVICES AGREEMENT: 03/25/2019**

This Study Transfer Agreement is entered into, effective as of the “Effective Date” set forth above, by and between Medrio, Inc., a Delaware corporation, with offices at 345 California St, Suite 325, San Francisco, CA 94104, the transferor identified above (“Transferor”), and the transferee identified above (“Transferee”) with respect to the study (the “Study”) that is the subject of the Order Form identified above (the “Order Form”). For and in consideration of the mutual covenants set forth herein, and for other good and valuable consideration, the parties hereby agree as follows:

1. Assignment of Order Form. As of the Effective Date, Transferor hereby transfers, assigns and conveys to Transferee all of Transferor's right, title and interest in, to and under the Order Form.

2. Assumption of Order Form.

a. Assumption. As of the Effective Date, Transferee hereby accepts, assumes and agrees to perform, fulfill and comply with all covenants and obligations to be performed, fulfilled or complied with by Transferor pursuant to the Order Form accruing on and after the Effective Date, and confirms that as of the Effective Date it shall be deemed a party to the Order Form and agrees to be bound by all of the terms of the Order Form and to undertake all the obligations of Transferor set forth therein.

b. References in Order Form. Transferee and Medrio hereby agree that all references in the Order Form to “Customer” shall be deemed references to Transferee. For all purposes under the master services agreement entered into by and between Medrio and Transferee, the Order Form will be deemed fully executed by Medrio and Transferee.

c. Receipt of Order Form. Transferee hereby acknowledges and confirms that it has received a copy of the Order Form.

d. Transferor Obligations. Transferor shall remain responsible for and shall perform all of Transferor's obligations under or with respect to the Order Form accruing prior to the Effective Date. Medrio agrees to release and discharge Transferor from any future obligations under the Order Form upon Transferee's undertaking from the Effective Date to perform and be bound by the terms of the Order Form.



3. Consent to Assignment. Medrio hereby consents to Transferor's conveyance and assignment of its right, title and interest in, to and under the Order Form to Transferee pursuant to this Study Transfer Agreement, to be effective as of the Effective Date.

4. Binding Effect. This Study Transfer Agreement shall be binding upon, and inure to the benefit of the parties hereto and their respective successors and assigns.

5. Entire Agreement. This Study Transfer Agreement shall constitute the entire agreement between the parties hereto with respect to the subject matter of this Study Transfer Agreement and supersedes all prior agreements, understandings, negotiations, representations, and discussions, whether verbal or written, of the parties, pertaining to that subject matter.

6. Severability. If any provision of this Study Transfer Agreement is determined to be illegal or unenforceable, all other provisions shall nevertheless be effective.

7. Governing Law. This Study Transfer Agreement shall be governed by and construed in accordance with the laws of the State of California without regard to any principles of law that would refer any matter relating to it to the laws of another jurisdiction.

8. Counterparts. This Study Transfer Agreement may be executed in several counterparts and all such executed counterparts shall constitute one document, binding on all of the parties hereto, notwithstanding that all of the parties hereto are not signatories to the original or to the same counterpart. This Study Transfer Agreement may be executed by electronic signatures and such signatures will be deemed to bind each party as if they were originals.

IN WITNESS WHEREOF, Transferor, Transferee and Medrio have executed and delivered this Study Transfer Agreement, effective as of the Effective Date.

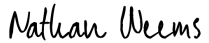
**Medrio, Inc.**

Signature

Name

Title:

Date:

DocuSigned by:  
  
 22BF97EEB74347B...  
 Nathan Weems  
 CFO  
 4/23/2019

**Transferor:**

Signature


Name

Title:

Date:

Cindy Henderson

Print Full Name:  
 DocuSigned by:



FB595652D3304CB...

Cindy Henderson

Executive VP, Strategic Development

4/22/2019

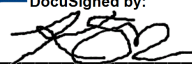
**Transferee:**

Signature

Name

Title:

Date:

Kyle Makofka  
 Print Full Name:  
 DocuSigned by:  
  
 825CD24E9CA24A4...  
 Kyle Makofka  
 CEO  
 4/22/2019

# EXHIBIT C





## MEDRIO, INC. MASTER SERVICES AGREEMENT

**CUSTOMER:** Topstone Research, Inc. a Ontario corporation

**ADDRESS:** 1 Eva Road, Suite 109, Toronto, ON M9C 4Z5, Canada

**EFFECTIVE DATE:** September 27, 2016

This Master Services Agreement (which, with any Order Form, as defined below, shall be referred to herein as the "Agreement") is entered into, effective as of the "Effective Date" set forth above, by and between Medrio, Inc., a Delaware corporation, with offices at 345 California St, Suite 325, San Francisco, CA 94104, and the customer identified above ("Customer"). For and in consideration of the mutual covenants set forth herein, and for other good and valuable consideration, the parties hereto agree as follows:

### 1. SERVICES AND SUPPORT.

a. Service. Medrio shall provide hosted services consisting of web-based access to Medrio's proprietary tools as further described in the attached Medrio Order Form, and any other subsequent order forms fully executed by the parties after the Effective Date (each, an "Order Form") and related support services (collectively, the "Services"). A separate Order Form shall be required for each study (or groups of studies, where expressly stated in the Order Form) or other services for which Customer seeks to use the Services. All Order Forms shall be governed by, and made a part of, this Agreement.

b. Equipment. Customer shall be responsible for obtaining and maintaining all equipment and ancillary services needed to connect to, access or otherwise use the Services (collectively, "Equipment"), and for ensuring that the Equipment is compatible with the Services and complies with the specifications in Medrio's then-current published policies. Customer also shall be responsible for maintaining the security of the Equipment, its account, all passwords and files, and for all use of the Services through its registered account.

c. Browser Support. Medrio will provide a list of supported browsers in the documentation with each release. Medrio reserves the right to require new browsers for new functionality. Medrio is not required to support browsers that are no longer supported by their original developers. Medrio will provide reasonable notice when deprecating support for a particular browser.

d. Support. Subject to the terms hereof, Medrio shall provide Customer with Level-2 technical support (or other support that may be agreed to on an Order Form), through e-mail or telephone, in accordance with the terms of this Agreement. Level-2 means Medrio supports study designers, builders, and administrators, and does not provide support directly to site users and study subjects. Medrio shall provide 99.5% Uptime (24x7x365) of the Services, per calendar month, excluding regularly scheduled maintenance times and excluding outages beyond Medrio's control (such as those caused by Customer's computers or connectivity, or a general internet failure). As used herein, "Uptime" means availability and access to the Services by Customer.

d. Upgrades. Customer understands and agrees that upgrades to the Service may be made in Medrio's sole discretion.



**2. STUDIES.** The terms of each Order Form shall apply solely to the study (or group of studies) identified in such Order Form. Upon completion of each study, Customer shall notify Medrio and Medrio will archive the study or group of studies. Other arrangements such as maintaining the study live after completion may be made on request and subject to Medrio's then-current policies with respect thereto.

**3. REGISTRATION; LOG-IN INFORMATION.** Customer shall be given log-in user names and initial passwords (the "Log-In Information"). Customer shall be responsible for maintaining the confidentiality and security of its Log-In Information, and shall be fully responsible for all activities which occur as the result of access using the Log-In Information. Customer shall immediately notify Medrio at [security@medrio.com](mailto:security@medrio.com) of any actual or suspected unauthorized use of its Log-In Information or similar breach of security.

**4. FEES.** Unless otherwise stated in the Order Form, Medrio shall invoice Customer electronically (or at Customer's request, in hard copy) at the beginning of the calendar month during which the Services shall be performed. All undisputed invoices shall be paid within thirty (30) days of the date of invoice. In the event of an error in any invoice, no adjustment shall be made unless Customer has contacted Medrio in writing (which may be via e-mail to [invoicing@medrio.com](mailto:invoicing@medrio.com) with confirmed receipt) within sixty (60) days of the date of the disputed invoice. Undisputed and unpaid invoices are subject to a finance charge of 1.5% per month on any outstanding balance, or the maximum permitted by law, if lower, plus all expenses of collection. Customer shall be responsible for all duties, withholdings and taxes associated with the Services other than taxes based on Medrio's net income. Any discounts provided by Medrio to Customer in return for "up-front payment" must be paid within 60 days of invoice to be earned, otherwise the discounts will be reversed from applicable invoices and Customer will be responsible for undiscounted fees.

**5. RESTRICTIONS ON USE.** This is a contract for services only. The software used to provide the Services shall be installed, accessed and maintained only by or for Medrio; no license is granted in it. Customer shall not, directly or indirectly: reverse engineer, decompile, disassemble or otherwise attempt to discover the source code, object code or underlying structure, ideas or algorithms of the Services or any software or documentation related to the Services ("Software"); modify, translate, or create derivative works based on the Services or any Software; copy, rent, lease, distribute, pledge, assign, or otherwise transfer or encumber rights to the Services or any Software; or use the Services or any Software for timesharing or service bureau purposes or otherwise for the benefit of a third party.

**6. CONFIDENTIAL INFORMATION.**

a. Definitions. As used in this Agreement, "Confidential Information" means all Clinical Data and Service Data, and all other information that one party and/or its affiliates (the "Receiving Party") receives from the other party and/or its affiliates (the "Disclosing Party") which is either marked "Confidential" or should be reasonably understood to be confidential. "Service Data" shall mean all data contained in the Services including but not limited to configuration information, usage information, access logs, Clinical Data and other Customer-entered data. "Clinical Data" shall mean all data entered by Customer or third parties in connection with the Services provided hereunder that is based on direct observation of, or reporting by or otherwise directly related to, a test subject/sample.

b. Obligations. The Receiving Party shall: (i) take reasonable precautions to protect all Confidential Information, and (ii) not use (except as expressly permitted herein) or divulge to any third person any such Confidential Information. Except with respect to Service Data, the Disclosing Party agrees that the foregoing shall not apply three (3) years after disclosure or if the Receiving Party can document that the information (a) is or has become generally available to the public; (b) was in its possession or known by it prior to receipt from the Disclosing Party; (c) was rightfully disclosed to it by a third party; (d) was independently developed without use of



any Confidential Information of the Disclosing Party; or (e) is required by law or regulatory or judicial order to be disclosed.

c. Medrio's Use of Service Data. The parties understand that in supporting the Services, Medrio may require access to the Service Data. Medrio may therefore access the Service Data in order to (i) support Customer's use of the Services, (ii) ensure the Services are operating correctly, and (iii) to gather data which enables Medrio to improve the Services. All such data shall be protected and managed in accordance with the requirements of this Section 6. In no event may Medrio provide the Clinical Data to any third party unless required by regulation or law. subject.

## 7. TERM AND TERMINATION.

a. Term. This Agreement shall commence on the Effective Date and shall continue for one (1) year (the "Initial Term"), and then automatically renew for subsequent one-year terms (each, a "Renewal Term"), unless one party notifies the other, no less than sixty (60) days prior to end of the Initial Term or any Renewal Term, of its intention not to renew, or unless otherwise terminated in accordance with this Agreement. Notwithstanding the foregoing, in the event that either party notifies the other party of its intention not to renew, the Agreement shall not terminate until the conclusion of all studies commenced under Order Forms fully executed as of the date of notice of non-renewal. The Initial Term and any Renewal Term(s) shall collectively be referred to herein as the "Term."

b. Termination for Cause. Either party may terminate this Agreement in the event of breach of a material obligation by the other party if such breach remains uncured to the reasonable satisfaction of the non-breaching party thirty (30) days after written notice specifying the breach. Either party may terminate this Agreement immediately by written notice if the other party becomes insolvent, is dissolved or liquidated (except for reorganization), makes a general assignment for the benefit of its creditors, files or has filed against it a petition for bankruptcy, or has a receiver appointed for a substantial part of its assets.

c. Other Termination by Customer. Customer may terminate this Agreement with (30) thirty days written notice. In the event of any termination requested by Customer under this Subsection 7(c), there shall be no refund of any pre-paid amounts, provided however that Medrio shall provide a credit of such unused pre-paid amounts to any future Order Forms.

8. **COMPLIANCE WITH APPLICABLE LAWS.** Each party shall comply with all laws and regulations applicable to the Services. If Customer is conducting studies in the US, then this compliance includes but is not limited to the requirements of the Health Insurance Portability and Accountability Act ("HIPAA") governing Personal Health Information ("PHI"), as defined in the Privacy Rule and the Security Rule of HIPAA (collectively, "Applicable Laws"). When using the Services, Customer shall ensure that its staff is fully trained in handling all PHI in compliance with all Applicable Laws, that PHI collected by Customer is correctly designated as such, and that appropriate controls on access to and use of the Services are implemented and monitored by Customer. Customer understands and agrees that Medrio shall have no responsibility or liability of any kind relating to the dissemination or use of any Clinical Data or any material derived from any Clinical Data once it leaves the direct control of Medrio (e.g., by screen shot, export, report, etc.). Customer shall not remove or export from the United States or allow the export or re-export of the Services, or any direct product thereof, in violation of any restrictions, laws or regulations of the United States Department of Commerce, the United States Department of Treasury Office of Foreign Assets Control, or any other United States or foreign agency or authority.

## 9. INDEMNITIES.



a. Medrio. Medrio hereby agrees to indemnify, defend and hold harmless Customer and its parents, subsidiaries, affiliates, officers, directors and employees, from all losses, liabilities, costs, damages, penalties, fines and expenses, including reasonable attorneys' fees (collectively, "Losses") arising from any and all third-party claims, demands, threats, suits or proceedings (each, a "Claim") arising from any and all Claims arising from any act or omission of Medrio in breach of this Agreement, or from any allegation that the Services infringe, violate or misappropriate the intellectual property rights of any third party.

b. Customer. Customer agrees to indemnify, defend and hold Medrio and its parents, subsidiaries, affiliates, officers, directors and employees, harmless from all Losses arising from any and all Claims arising from any act or omission of Customer in breach of this Agreement, including but not limited to any violation of any Applicable Law in connection with Customer's use of the Services.

c. Process. If any Claim is asserted or instituted with respect to which Customer or Medrio is entitled to indemnification, then the party seeking indemnification shall promptly notify the indemnifying party of all material details of such Claim known to it. The party seeking indemnification shall cooperate with the indemnifying party in the defense of the Claim, and shall not compromise or otherwise settle any such Claim without the indemnifying party's prior written consent.

**10. AUDITS.** Upon reasonable notice and during regular business hours, Customer or its agents may inspect Medrio's facilities and may audit its records, including contracts, copies, files, records, accounts and other documents and materials in Medrio's possession or under its control, relating to the Services provided to Customer. Medrio shall make available all such records and shall provide commercially reasonable assistance in the inspection or audit. Customer's right to audit shall continue for one (1) year after termination or expiration of this Agreement, or longer if required by Applicable Laws.

**11. PROPRIETARY RIGHTS.** Customer acquires only the right to use the Services, and does not acquire any rights of ownership whatsoever in or to the Services, or any technology used to provide the Services. All rights, title, and interest in and to the Services and (other than content created as a result of use of the Services by Customer), the material on the Medrio Web site, including without limitation all intellectual property rights therein, shall at all times exclusively remain with Medrio. All rights not expressly granted to Customer under this Agreement are reserved to Medrio. Customer shall retain all rights, including ownership of all intellectual property rights to content created or uploaded by Customer while using the Services.

**12. WARRANTIES.** Each party represents and warrants that it has the power and authority to enter into and fully perform its obligations under this Agreement. Medrio represents and warrants that it shall use reasonable efforts consistent with prevailing industry standards to maintain the Services in a manner that minimizes errors and interruptions in the Services.

**13. DISCLAIMERS OF WARRANTIES.** EXCEPT AS EXPRESSLY STATED HEREIN, AND TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, MEDRIO MAKES NO, AND HEREBY DISCLAIMS, ANY REPRESENTATION, WARRANTY OR GUARANTY WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SERVICE.

**14. LIMITATION OF LIABILITY.**

EXCEPT WITH RESPECT TO (i) FEES PAYABLE UNDER SECTION 4, (ii) INDEMNIFIED CLAIMS UNDER SECTION 9, (iii) BREACH OF SECTION 6 (CONFIDENTIAL INFORMATION), AND (iv) INFRINGEMENT OF A PARTY'S INTELLECTUAL PROPERTY RIGHTS, NEITHER PARTY OR ITS OFFICERS, AFFILIATES, REPRESENTATIVES, SUPPLIERS, CONTRACTORS OR EMPLOYEES SHALL BE LIABLE UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY FOR ANY AMOUNTS THAT, TOGETHER WITH AMOUNTS ASSOCIATED WITH ALL OTHER CLAIMS, EXCEED THE FEES PAID BY CUSTOMER TO MEDRIO FOR THE SERVICES UNDER THE APPLICABLE ORDER FORM IN THE TWELVE (12)



MONTHS PRIOR TO THE ACT THAT GAVE RISE TO THE LIABILITY. IN NO EVENT SHALL EITHER PARTY BE DIRECTLY LIABLE TO THE OTHER PARTY FOR ANY PUNITIVE OR EXEMPLARY DAMAGES.

**15. SECURITY OF DATA.** During the Term Medrio shall maintain a comprehensive data security program, which shall include the following: (a) Medrio shall have a written information security plan that fully documents the content and implementation of Medrio's administrative, technical, and physical safeguards to protect the Service Data; (b) Medrio shall conduct periodic risk assessments (at a minimum, annually) and use the results of those risk assessments to update its security program as needed; and (c) Medrio shall notify Customer within a reasonable time period, but within no more than seventy-two (72) hours, if it has reason to suspect that there has been unauthorized access to or acquisition of any Service Data. All Medrio employees and contractors with access to Service Data shall be trained in procedures to ensure compliance by Medrio with the obligations set forth in Section 8 (Compliance with Applicable Laws).

**16. INSURANCE.** Medrio represents and warrants that it has a valid policy of workers' compensation insurance for protection against any injuries suffered by Medrio's agents, employees, or contractors while performing its obligations hereunder, and commercial general liability insurance for protection against any personal property damage or liability suffered by Customer or any third party as a result of acts of omission of Medrio or its agents, employees or contractors. Medrio shall provide Customer with evidence of such insurance coverage, upon the reasonable written request of Customer at any time during the Term.

**17. INDEPENDENT CONTRACTORS.** For all purposes hereof and in the performance of its obligations under this Agreement, Medrio is and shall remain an independent contractor. Nothing in this Agreement shall be deemed or construed to create an employer/employee, joint venture, or partnership relationship between Medrio and Customer. Neither party shall have any authority to make any promise, representation, or contract of any nature on behalf of the other party.

**18. PUBLICITY.** Neither party shall issue any press release or other publicity without the prior written consent of the other (which may be given via e-mail), provided however that Medrio may during the Term include Customer on its customer list.

**19. ASSIGNMENT.** Neither party may assign or otherwise transfer its rights under this Agreement, including the license granted hereunder, without the prior written consent of the other party (which may be given via e-mail), provided however that either party may assign this Agreement, provided that it gives written notice, in connection with a merger, sale or acquisition of it, or a sale of all or substantially all the assets to which this Agreement relates.

**20. GENERAL.** If any provision of this Agreement is found to be unenforceable or invalid, that provision shall be limited or eliminated to the minimum extent necessary to allow this Agreement to remain in full force and effect and enforceable. This Agreement, with any Order Form that is attached, or that is executed by the parties and effective on or after the Effective Date, is the complete and exclusive statement of the mutual understanding of the parties and supersedes and cancels all previous written and oral agreements, communications and other understandings relating to the subject matter of this Agreement. All waivers and modifications must be in a writing signed by both parties, except as otherwise provided herein. This Agreement shall be governed by the laws of the State of California without regard to any conflict of laws principle that would refer the governance, interpretation or construction of this Agreement to the laws of another jurisdiction. Each party irrevocably submits to the personal jurisdiction of the courts located in San Francisco County, California, and agrees that such courts shall have exclusive jurisdiction with respect to this Agreement, and that venue shall be proper in any such court. Upon termination or expiration of this Agreement, the following clauses shall survive: Sections 4 (as to unpaid amounts), 5, 6, 7(c) (last sentence), 8 through 14, inclusive, and this Section 20. Upon termination, Medrio may, but is not obligated to, delete archived Service Data (to the extent permitted under Applicable Laws). In the event




of any dispute under this Agreement, the parties shall work in good faith, for a period of no less than thirty (30) days from the date of written notice of such dispute, to resolve the matter informally, prior to the commencement of any formal proceeding. All notices under this Agreement shall be in writing and shall be deemed to have been duly given: upon receipt, if delivered personally or by a recognized overnight delivery service; when receipt is electronically confirmed, if transmitted by e-mail; and upon receipt, if sent by certified or registered mail, return receipt requested. All notices to Medrio shall be sent to 345 California St, Suite 325, San Francisco, CA 94104, Attn: Legal Dept.; e-mail notices shall be sent to [notices@medrio.com](mailto:notices@medrio.com). All notices to Customer shall be sent to the address set forth below.

**Medrio, Inc.**

Signature \_\_\_\_\_  
 Name \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

**Topstone Research, Inc.**

Signature  \_\_\_\_\_  
 Name Shaheen Limbada  
 Title: Managing Director  
 Date: 28-SEP-2016

cn=Shaheen Limbada, Managing  
 Director, o=Topstone Research Inc., ou,  
 email=shaheen.limbada@topstoneresear  
 ch.com, c=CA  
 2016.09.28 13:19:56 -04'00'

Address for Legal Notices:

1 Eva Road, Suite 109  
Etobicoke, ON M9C 4Z5  
 Attn: Shaheen Limbada

E-mail Address for Legal Notices:

shaheen.limbada@topstoneresearch.com





## EXHIBIT A

### M-1 Order Form

#### BILLING INFORMATION

Customer	Topstone Research
Study	Phase 2B Study
Medrio Account Manager	Angela Dair
Study Initiation Date (estimated)	10/1/2016
Billing Commencement Date	Upon Signature
Customer Billing Contact	Bilal Muhammad
Customer Email	bilal.muhammad@topstoneresearch.com

#### TECHNICAL PARAMETERS

Number of Login Users	Medrio caps the number of users to prevent misuse. Please contact your Account Manager if you will exceed these maximums. Studies up to 12 months duration: 200 Studies greater than 12 months duration: 600
Enrolled Subjects	Unlimited
Data Points	250,000 per study maximum ( <i>more can be purchased as a separate module</i> ) Overage Fees: 10% of base monthly price for every 250K data points over original 250K
Standard Technical Support	Level 2 included: 6am to 6pm PST by phone and 24/5 email, M-F, all in English
Dictionary Coding	YES Does not include license to dictionaries
eCRF File Attachments	NO
ePRO	NO
Randomization	YES
24/7 Technical Support	NO 24/7 support can be purchased for an additional 10%

#### SERVICE CONFIGURATION

PRODUCT NAME	CHARGE	TOTAL
M-1	11 months @ \$3,600 per month*	Initial Payment: \$39,600.00

\*10% discount reflected; 5% subscription discount and 5% partner program discount.

Initial Payment Total	\$39,600.00
Contract Lifetime	11 months
Total Contract Value	\$39,600.00



PROFESSIONAL SERVICES

*Hourly work: hours in addition to the amounts specified in this Order Form are billable under this Order Form, but only when pre-authorized.*

*Reasonable pass-through expenses for travel and other incidentals associated with professional services such as training will be billed separately.*



# **EXHIBIT D**



**DLA Piper LLP (US)**  
 200 South Biscayne Boulevard  
 Suite 2500  
 Miami, Florida 33131-5341  
 www.dlapiper.com

Christopher George Oprison  
 chris.oprison@dlapiper.com  
 T 305.423.8522  
 F 305.657.6366

**September 3, 2020**

<u>VIA EMAIL</u> Benjamin B. Au, Esq. Durie Tangri 953 East 3rd Street Los Angeles, CA 90013 bau@durietangri.com	<u>VIA EMAIL</u> David F. McGowan, Esq. Durie Tangri 217 Leidesdorff Street San Francisco, CA 94111 dmcgowan@durietangri.com
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**Re: Return of Hemostemix Data from Medrio Inc.**

Dear Counsel:

As you know, my firm represents Hemostemix Inc. This letter follows an August 27, 2020 letter from your colleague, Ragesh Tagri regarding your client Medrio, Inc., our call on Monday, August 31, 2020 and your email of September 2, 2020. As we discussed on our call, obtaining return of Hemostemix's clinical trial data for all active clinical trial sites that has been hosted by Medrio is of paramount importance. Years of work and millions of dollars have been invested by Hemostemix in the clinical trial. Aspire Health Science, LLC ("Aspire") has interfered with the clinical trials and continues to do so by, among other things, impeding Hemostemix's access to its own data.

By way of background, Hemostemix is an Alberta, Canada corporation that conducts business as a clinical-stage autologous cell-therapy biotechnology company. Its principal business is to develop, manufacture, and commercialize blood-derived cell therapies to treat various diseases not addressed by current therapies. Hemostemix owns the intellectual property rights to ACP-01, its lead product, which is used for the treatment of obstructed arteries and other vascular diseases. Hemostemix is also the FDA-approved Clinical Trial Sponsor for ACP-01 treatment of CLI, a severe form of peripheral artery disease (PAD) caused by reduced blood flow to the legs. Hemostemix is and always has been the Phase II Clinical Trial Sponsor of this trial. It is the *only entity* approved by the FDA to enroll patients at clinical trial sites across the United States. As the Clinical Trial Sponsor, Hemostemix is legally responsible for all aspects of the Clinical Trial under FDA and Health Canada regulations, including the integrity and accuracy of the clinical trial data.

Hemostemix has requested the return of or access to data *owned by Hemostemix* that is hosted by Medrio pursuant to a Master Services Agreement with Hemostemix dated March 25, 2019 ("MSA") and Study Transfer Agreement dated March 26, 2020 ("STA") (collectively, "Agreements"). Pursuant to the Agreements, Medrio agreed to provide hosting services for Hemostemix's clinical trial data and service data. According to your letter of August 27, 2020,



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 David F. McGowan, Esq.  
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 Page Two

Medrio now refuses to return Hemostemix's data. Medrio cites "Aspire Health Science, LLC's instructions to Medrio not to provide that data to Hemostemix" and "multiple lawsuits" as grounds for its refusal. Medrio's position is unfortunate and incorrect.

As discussed on our call, Medrio's contractual obligation to return and/or provide access to Hemostemix's data is independent of any pending litigation and independent of any obligation Medrio claims it owes to Aspire. Moreover, as we discussed on our call, even Aspire has conceded (and is estopped from denying) Hemostemix owns all intellectual property, including clinical data, relating to the ACP-01 trial.<sup>1</sup> Nothing under FDA regulations, statute or contractual agreement transfers ownership of Hemostemix's data to Aspire. Nor could it. Aspire, the CRO with only those rights and authority expressly delegated to it through the licensing agreement, has tortiously interfere with Hemostemix's ability to obtain return of or access to its own clinical data. Aspire is engaging in extortionate conduct, threatening lawsuits or other consequences to entities (including, we suspect, Medrio) that hold Hemostemix's data should any of those entities return the data or provide Hemostemix access to its own data. Aspire and its Florida counsel have gone so far as to instruct at least one holder of Hemostemix's data (Accudata, a biostatistician contracted by Hemostemix to conduct a midpoint analysis and issue a report) to "return *or destroy*" (emphasis added) the clinical trial data despite having no contractual grounds for doing so and despite the pendency of litigation in Florida, and then-anticipated litigation in Delaware.<sup>2</sup> Aspire's conduct

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<sup>1</sup> Not only does Aspire concede in the Florida Complaint that Hemostemix owns all intellectual property related to ACP-01 (as it must, given Hemostemix as Sponsor is statutorily charged with ultimate accountability over the data), but both the original and amended licensing agreement conclusively establish that Hemostemix owns the clinical trial data. Both make clear that Aspire, as the contract research organization ("CRO"), was granted only a *license* to use Hemostemix's Technology and to conduct the clinical trial. Under both agreements, Hemostemix remains the owner of the "Technology." "**Technology**" is broadly defined to mean "the **Intellectual Property** owned by Hemostemix for ACP-01, and includes all "Improvements," *whether developed by Hemostemix or Aspire.*" (emphasis added). "**Intellectual Property**," in turn, expressly includes "**Confidential Information**," which expressly includes "**Patient Data**," and "**Patient Data**" expressly includes "any and all data that is (a) related to the reaction of patients to treatment using the Product and that is also (b) created, obtained or kept by any Treatment Affiliates, Aspire or its Affiliates or Subcontractors." There can be no dispute that Hemostemix now owns, always has owned, and so long as it continues in its role as FDA-approved Sponsor *will own* all clinical trial data in whatever form, regardless of what temporary custodian may hold that data at any given time.

<sup>2</sup> According to one email exchange, Aspire's representative Reg Cooper asked Doug Milikien of Accudata to "confirm in a response that all materials related to the analysis have been returned *or destroyed* and you are no longer holding copies of the data as per the terms of our agreement" (emphasis added) despite there being no provision in any agreement between Aspire and Accudata referencing or permitting, much less requiring Accudata to destroy Hemostemix's data. Nor could there be any such provision given that the data is owned by Hemostemix. Likewise, in an email dated July 15, 2020, Florida counsel for Aspire admitted to the undersigned that "Aspire's counsel advised Accudata's counsel that Accudata is *contractually mandated* to either *destroy* or return to Aspire the clinical trial data, but nothing more," (emphasis added) despite, again, there being no agreement between Aspire and Accudata



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David F. McGowan, Esq.  
September 3, 2020  
Page Three

is wrongful and will be separately adjudicated in the Florida and Delaware actions. But, as you know, a complete resolution in either forum could be months if not years away. In the interim, the results of the clinical trials would become obsolete and unusable, causing Hemostemix harm quantified conservatively in the tens of millions of dollars.

Accordingly, we disagree with the statement in your email of September 2, 2020—neither the Florida nor Delaware actions “provide the fastest path towards resolution of the underlying dispute.” Rather, Medrio’s prompt compliance with its contractual obligations to Hemostemix provides the most expeditious pathway to resolution, not protracted litigation with Aspire or any other custodian of Hemostemix’s data. **Hemostemix therefore again demands immediate return of its clinical trial data that Medrio is hosting.** Hemostemix is prepared to take whatever action is necessary to recover *all* of its data from *all* sources, including an action under the MSA and STA in federal court in Northern California or other appropriate jurisdiction. We would prefer to avoid having to do so, and I am certain Medrio would as well when we have a more amicable option available to us.

As proposed previously by Hemostemix to Medrio’s Chief Operating Officer, Hemostemix would agree to indemnify Medrio for expenses incurred or losses sustained in defending an action that may be brought by Aspire. Hemostemix has no legal or other obligation to make this offer, and does so subject to and without waiving any rights, claims, or other relief available to it. Pragmatically, Hemostemix is willing to entertain any reasonable means of obtaining immediate return of its data. If Medrio will, in good faith, agree to the prompt return Hemostemix’s data, Hemostemix will provide, subject to confidential treatment under Fed. R. Evid. 408, a proposed written indemnification agreement for your consideration. Each day that passes during which parties are complicit in Aspire’s misconduct causes harm to Hemostemix, including preventing Hemostemix from fulfilling its disclosure and reporting obligations and interfering with the ability to continue and complete the clinical trials.

Finally, I raised several questions during our call about which you both indicated you would consult with your client. As part of our good faith negotiations, we would appreciate a response to the following:

1. Does Medrio have a Master Services Agreement with Aspire and, if so, will Medrio produce it to Hemostemix without legal process?

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referencing *much less mandating* destruction of data, and the only expressly permitted form of data disposition in the agreement was returning the data, not destroying it.



Benjamin B. Au, Esq.  
David F. McGowan, Esq.  
September 3, 2020  
Page Four

2. Does Medrio have a Study Transfer Agreement with Aspire and, if so, will Medrio produce it to Hemostemix without legal process?
3. Is Medrio willing to share Aspire's written instructions not to produce data to Hemostemix that is referred to in Mr. Tangri's letter of August 27?
4. Has Medrio provided any clinical trial data to Aspire?
5. Has Aspire at any time directed or encouraged Medrio to destroy any of the hosted data that is the subject of this letter?

Please advise whether you wish to have a call to discuss the contents of this letter. Absent that, we would appreciate receiving confirmation by close of business **Friday, September 4, 2020**, that Medrio intends to return Hemostemix's data, Medrio's position on an indemnification arrangement, and responses to the foregoing questions.

Thank you for your consideration. I look forward to hearing from you.

**DLA Piper LLP (US)**

/s/ Christopher Oprison  
Christopher G. Oprison

cc: Ragesh K. Tangri, Esq.  
Durie Tangri

Matthew Denn, Esq.  
DLA Piper LLP (US)